

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

VAIBHAV DOSHI, Individually and on  
Behalf of All Others Similarly Situated,

Plaintiff,  
v.

TOKAI PHARMACEUTICALS, INC.,  
JODIE POPE MORRISON, and LEE H.  
KALOWSKI,

Defendants.

Case No.:

CLASS ACTION COMPLAINT FOR  
VIOLATIONS OF THE FEDERAL  
SECURITIES LAWS

JURY TRIAL DEMANDED

Plaintiff Vaibhav Doshi (“Plaintiff”), by and through his attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff’s information and belief is based upon, among other things, his counsel’s investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Tokai Pharmaceuticals, Inc. (“Tokai” or the “Company”), with the United States (“U.S.”) Securities and Exchange Commission (“SEC”); (b) review and analysis of press releases and media reports issued by and disseminated by Tokai; and (c) review of other publicly available information concerning Tokai.

**NATURE OF THE ACTION AND OVERVIEW**

1. This is a class action on behalf of purchasers of Tokai securities between June 24, 2015 and July 25, 2016, inclusive (the “Class Period”), seeking to pursue remedies under the Securities Exchange Act of 1934 (the “Exchange Act”).

2. Tokai is a biopharmaceutical company focused on developing and commercializing innovative therapies for prostate cancer and other hormonally-driven diseases. The Company’s

lead drug candidate is galeterone, an oral small molecule that was, at all relevant times, in various clinical trials for the treatment of patients with metastatic castration-resistant prostate cancer.

3. Tokai was founded in 2004 and is headquartered in Boston, Massachusetts. The Company's stock trades on the NASDAQ under the ticker symbol "TKAI."

4. Throughout the Class Period, Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) there were significant structural problems with the trial design for Tokai's pivotal Phase 3 galeterone study, ARMOR3-SV; (ii) consequently, ARMOR3-SV was unlikely to succeed in meeting its primary endpoint; (iii) as a result, commercialization of galeterone was less likely and/or imminent than Tokai had led investors to believe; and (iv) as a result of the foregoing, the Company's financial statements, as well as Defendants' statements about Tokai's business, operations, and prospects, were false and misleading and/or lacked a reasonable basis.

5. On November 2, 2015, Richard Pearson published an article on the investment website *Seeking Alpha*, entitled "What's Wrong With Tokai Pharmaceuticals?" (the "Pearson Report"). The Pearson Report summarized the author's findings as follows:

### **Summary**

- Tokai's attempt at a Phase 3 trial is based on data from just 6 patients out of 87 in Phase 2, based on after-the-fact cherry picking of data.
- Tokai dramatically changed its trial design between Phase 2 and Phase 3, and the FDA has already warned Tokai about problems with its trial design.
- Insider selling has been rampant ahead of preliminary data in 2016.
- Tokai just filed a massive \$150 million S3 registration statement in order to raise money before Phase 3 results are known.
- Expect 60-70% near-term downside in the stock.

6. The Pearson Report described structural problems with the design of the Company's ARMOR3-SV trial, and concluded that "**Because of its trial design, Tokai is virtually guaranteed to fail in Phase 3 and the stock will fall to cash value, a decline of at least 60%.**" (Emphasis in original.)

7. On this news, Tokai's share price fell \$0.07, or 0.63%, to close at \$10.98 on November 2, 2015.

8. Then, on July 26, 2016, Tokai announced plans "to discontinue the ARMOR3-SV clinical trial, our pivotal Phase 3 study" of galeterone. The Company stated, in part:

Based on a review of all safety and efficacy data, the DMC [data monitoring committee] determined that the ARMOR3-SV trial will likely not succeed in meeting its primary endpoint of demonstrating an improvement in radiographic progression-free survival ("rPFS") for galeterone versus enzalutamide in AR-V7 positive mCRPC. In making its recommendation, the DMC did not cite any safety concerns with galeterone in the trial. ARMOR3-SV is the first pivotal clinical trial in mCRPC to prospectively select AR-V7 positive patients, a population we believe represents an unmet medical need and has an aggressive disease course.

We plan to analyze the unblinded study data in detail to evaluate potential paths for galeterone and our pipeline. We plan to present data from the trial in a scientific forum once fully available and analyzed.

We also intend to evaluate our ongoing ARMOR2 expansion in mCRPC patients with acquired resistance to enzalutamide, and our planned study in patients who rapidly progress on either enzalutamide or abiraterone acetate. We plan to allow all patients currently enrolled in the ARMOR2 and ARMOR3-SV trials to continue on therapy following consultation with their physicians and study investigators. The appropriate health authorities and clinical study investigators are being notified that ARMOR3-SV is being discontinued.

7. On this news, Tokai's share price plummeted by \$4.10, or nearly 79%, to close at \$1.10 on July 26, 2016.

8. On July 29, 2016, after the market closed, Tokai issued a press release entitled “Tokai Pharmaceuticals Announces Reduction in Force.” In the press release, the Company stated, in part:

Tokai Pharmaceuticals Inc. (NASDAQ: TKAI), a biopharmaceutical company focused on developing and commercializing innovative therapies for prostate cancer and other hormonally driven diseases, today announced that it is reducing its workforce by approximately 60 percent, to a total of 10 full-time equivalent employees, under a plan expected to be largely completed by the end of the third quarter of 2016. *This workforce reduction is designed to reduce operating expenses while the company conducts a comprehensive evaluation of strategic options for galeterone and its pipeline. . . .*

*“A reduction in force is a very difficult yet necessary step in light of the recent discontinuation of the ARMOR3-SV trial of galeterone in mCRPC,”* said Jodie Morrison, President and Chief Executive Officer of Tokai. “I would like to personally express my appreciation to each of the employees impacted by this decision for their commitment to the development of galeterone, as well as for their meaningful contributions to a program that has expanded the dialogue among the medical and patient communities about AR-V7 and advanced prostate cancer treatment options.”

(Emphases added.)

9. On this news, Tokai’s share price fell \$0.13, or 10.32%, to close at \$1.13 on August 1, 2016, the next trading day.

10. As a result of Defendants’ wrongful acts and omissions, and the precipitous decline in the market value of the Company’s securities, Plaintiff and other Class members have suffered significant losses and damages.

#### **JURISDICTION AND VENUE**

11. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. §78aa).

13. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1331(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa). Tokai's common stock trades on the NASDAQ, located within this Judicial District.

14. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

### **PARTIES**

15. Plaintiff, as set forth in the accompanying certification, incorporated by reference herein, purchased Tokai common stock during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

16. Defendant Tokai is a Delaware corporation with its principal executive offices located at 255 State Street, 6th Floor, Boston, Massachusetts 02109.

17. Defendant Jodie Pope Morrison ("Morrison") has served at all relevant times as Chief Executive Officer, President, and a Director of Tokai.

18. Defendant Lee H. Kalowski ("Kalowski") has served at all relevant times as Chief Financial Officer of Tokai.

19. Defendants Morrison and Kalowski are collectively referred to hereinafter as the "Individual Defendants."

### **SUBSTANTIVE ALLEGATIONS**

#### **Background**

20. Tokai is a biopharmaceutical company focused on developing and commercializing innovative therapies for prostate cancer and other hormonally-driven diseases. The Company's lead drug candidate is galeterone, an oral small molecule that was, at all relevant times, in various clinical trials for the treatment of patients with metastatic castration-resistant prostate cancer.

21. Tokai was founded in 2004 and is headquartered in Boston, Massachusetts.

**Materially False and Misleading  
Statements Issued During the Class Period**

22. The Class Period begins on June 24, 2015, when Tokai issued a press release entitled "Tokai Pharmaceuticals Announces Initiation of Phase 3 ARMO43-SV Trial of Galeterone in AR-V7 Positive Metastatic Castration-Resistant Prostate Cancer." The press release stated, in part:

"ARMOR3-SV represents an important step forward in bringing precision medicine to patients with prostate cancer, and we are pleased with the progress made by our valued collaborator Qiagen in readying the AR-V7 clinical assay for global implementation," said Jodie Morrison, President and Chief Executive Officer of Tokai. "With worldwide commercial rights to galeterone, our pivotal clinical trial on track to read out by the end of 2016, and a strong financial position, Tokai is well positioned to realize its mission of bringing new therapeutic treatment options to patients with prostate cancer."

...

"Based on the evidence reported thus far, a diagnostic tool that can predict patient responsiveness to certain therapies should lead to more informed treatment decisions and ultimately better care for prostate cancer patients," said Mary Ellen Taplin, M.D., Director of Clinical Research, Lank Center for Genitourinary Oncology, Dana-Farber Cancer Institute and lead U.S. investigator of ARMOR3-SV. "Given the encouraging clinical data reported to date for galeterone and the precision medicine approach being employed in Tokai's pivotal trial, this study has the opportunity to alter the treatment landscape for metastatic CPRC patients."

...

The company expects topline data from ARMOR3-SV to be available by the end of 2016.

23. On August 12, 2015, Tokai filed a Quarterly Report on Form 10-Q with the SEC, announcing the Company's financial and operating results for the quarter ended June 30, 2015 (the "Q2 2015 10-Q"). For the quarter, Tokai reported a net loss of \$8.96 million, or \$0.40 per diluted share, on zero revenue.

24. In the Q2 2015 10-Q, the Company stated, in part:

We have initiated our pivotal Phase 3 clinical trial of galeterone, which we refer to as ARMOR3-Splice Variant, or ARMOR3-SV, in metastatic CRPC patients whose tumor cells express AR-V7. In ARMOR3-SV, we are comparing galeterone to Xtandi® (enzalutamide) in 148 metastatic CRPC patients who have not received other second-generation oral therapies or chemotherapy for their CRPC. The primary endpoint of ARMOR3-SV is radiographic progression-free survival assessed by blinded independent central review. Selection of patients with AR-V7 is made using a clinical trial assay optimized for global use by our collaborator, Qiagen. Implementation of the clinical trial assay is ongoing and screening of eligible patients is expected to begin this quarter. The design of ARMOR3-SV is informed by feedback that we obtained from the U.S. Food and Drug Administration, or FDA, and the European Medicines Agency. We expect top-line data from ARMOR3-SV to be available by the end of 2016. We have been given fast track designation by the FDA for galeterone for the treatment of CRPC.

25. The Q2 2015 10-Q contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by the Individual Defendants, stating that the financial information contained in the Q2 2015 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

26. On August 12, 2015, Tokai also issued a press release entitled "Tokai Pharmaceuticals Reports Second Quarter 2015 Results." The press release stated, in part:

Tokai's business highlights for the quarter include the initiation of ARMOR3-SV, Tokai's pivotal Phase 3 clinical trial of galeterone in men with metastatic castration-resistant prostate cancer (mCRPC) whose tumor cells express the AR-V7 splice variant, which is a truncated form of the androgen receptor that has been associated with non-responsiveness to commonly-used oral therapies for mCRPC.

ARMOR3-SV is designed to evaluate whether administration of galeterone results in a statistically significant increase in radiographic progression free survival as compared to Xtandi® (enzalutamide) in 148 treatment-naïve mCRPC patients

whose prostate tumor cells express the AR-V7 splice variant. This trial represents the first pivotal trial in prostate cancer that employs a precision medicine approach for patient selection. The design and clinical rationale for ARMOR3-SV was presented last quarter at the 2015 Annual Meeting of the American Society for Clinical Oncology. Topline data from ARMOR3-SV are anticipated by the end of 2016.

...

“We believe that AR-V7 positive metastatic CRPC represents a significant unmet market opportunity, and that ARMOR3-SV has the potential to change the treatment landscape for metastatic CRPC patients by enabling treating physicians to make more informed treatment decisions,” said Jodie Morrison, President and Chief Executive Officer of Tokai. “We are pleased with our progress in initiating ARMOR3-SV globally, and with screening of patients beginning this quarter, we expect topline data from the study by the end of next year. *With worldwide rights to galeterone and a pipeline of candidates from our ARDA discovery platform, a strong financial position and pivotal data expected next year, we are well positioned to create value from Tokai’s pipeline* and achieve our mission of developing and delivering innovative therapies that provide hope and healing for patients living with cancer.”

(Emphasis added.)

27. On November 2, 2015, Richard Pearson published an article on the investment website *Seeking Alpha*, entitled “What’s Wrong With Tokai Pharmaceuticals?” The Pearson Report summarized the author’s findings as follows:

### **Summary**

- Tokai’s attempt at a Phase 3 trial is based on data from just 6 patients out of 87 in Phase 2, based on after-the-fact cherry picking of data.
- Tokai dramatically changed its trial design between Phase 2 and Phase 3, and the FDA has already warned Tokai about problems with its trial design.
- Insider selling has been rampant ahead of preliminary data in 2016.
- Tokai just filed a massive \$150 million S3 registration statement in order to raise money before Phase 3 results are known.
- Expect 60-70% near-term downside in the stock.

28. The Pearson Report described structural problems with the design of the Company's ARMOR3-SV trial, and concluded that "**Because of its trial design, Tokai is virtually guaranteed to fail in Phase 3 and the stock will fall to cash value, a decline of at least 60%.**" (Emphasis in original.)

29. On this news, Tokai's share price fell \$0.07, or 0.63%, to close at \$10.98 on November 2, 2015.

30. On November 10, 2015, Tokai filed a Quarterly Report on Form 10-Q with the SEC, announcing the Company's financial and operating results for the quarter ended September 30, 2015 (the "Q3 2015 10-Q"). For the quarter, Tokai reported a net loss of \$11.85 million, or \$0.53 per diluted share, on zero revenue, compared to a net loss of \$6.39 million, or \$2.71 per diluted share, on zero revenue for the same period in the prior year.

31. In the Q3 2015 10-Q, the Company stated, in part:

We are conducting a pivotal Phase 3 clinical trial comparing galeterone to Xtandi® (enzalutamide) in approximately 148 mCRPC patients whose prostate tumors express the AR-V7 splice variant. We refer to this clinical trial as ARMOR3-SV. We believe that the AR-V7 splice variant is the most common form of C-terminal loss, or the loss of the portion of the androgen receptor that contains the ligand-binding domain. C-terminal loss generally, and AR-V7 specifically, has been associated with non-response to commonly-used oral therapies for mCRPC. ARMOR3-SV is the first precision medicine based pivotal clinical trial in prostate cancer. Selection of patients with AR-V7 is made using a clinical trial assay developed by our collaborator, Qiagen Manchester Limited, or Qiagen. The design of ARMOR3-SV is aligned with feedback that we obtained from the U.S. Food and Drug Administration, or FDA, and the European Medicines Agency. We expect top-line data from ARMOR3-SV to be available by the end of 2016. We have been given fast track designation by the FDA for galeterone for the treatment of mCRPC.

32. The Q3 2015 10-Q contained signed certifications pursuant to SOX by the Individual Defendants, stating that the financial information contained in the Q3 2015 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

33. On November 10, 2015, Tokai also issued a press release entitled “Tokai Pharmaceuticals Reports Third Quarter 2015 Financial Results.” The press release stated, in part:

“This was an important quarter of progress for Tokai,” said Jodie Morrison, President and Chief Executive Officer of Tokai. “Active screening of patients in our ARMOR3-SV pivotal trial is underway, and we expect to report top-line results by the end of 2016. In parallel, under the experienced leadership of Lisa Taylor, ***we are making substantial progress in shaping our go-to-market strategy*** and engaging with clinical leaders throughout the world who recognize the significant need for new treatment options for patients who are unresponsive to existing therapies.”

Recent highlights include:

- ***Pivotal ARMOR3-SV Trial Underway:*** During the quarter, Tokai began screening patients for participation in ARMOR3-SV, the company’s pivotal Phase 3 clinical trial of galeterone, the first Androgen Receptor Degrader in clinical testing. ARMOR3-SV, the first pivotal trial in prostate cancer employing a precision medicine approach for patient selection, is evaluating whether administration of galeterone results in a statistically significant increase in radiographic progression-free survival as compared to Xtandi® (enzalutamide) in 148 treatment-naïve metastatic castration-resistant prostate cancer (mCRPC) patients whose prostate tumor cells express the androgen receptor splice variant-7 (AR-V7). AR-V7 is a truncated form of the androgen receptor that has been associated with non-response to commonly used oral therapies for mCRPC. The design of ARMOR3-SV is aligned with feedback obtained from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency, and top-line data for the trial are expected by the end of 2016.
- ***Expanded the Executive Team’s Commercial Expertise: Tokai continued to prepare its growing commercial organization for the anticipated launch of galeterone.*** Lisa Taylor joined the company during the quarter as Senior Vice President, Commercial Development, a newly created role. Ms. Taylor brings over two decades of experience in biopharmaceutical marketing, and was a member of the launch team for Xtandi® (enzalutamide) at Medivation Inc.

(Emphases added.)

34. On January 7, 2016, Tokai issued a press release entitled “Tokai Announces Update on ARMOR3-SV and Expanded Galeterone Clinical Development Program.” In the press release, Tokai stated, in part:

### ARMOR3-SV Update

Tokai is enrolling patients in its ARMOR3-SV study, a Phase 3 registration clinical trial of galeterone in AR-V7+ mCRPC. The company now expects to complete enrollment in this trial during the second half of 2016 and to have top-line data available by mid-2017. . . .

“With our rapidly growing number of open ARMOR3-SV clinical sites globally and the implementation of new recruitment initiatives, we believe in our ability to recruit to our revised guidance,” said Jodie Morrison, President and Chief Executive Officer of Tokai. “Interest in AR-V7 as a marker for resistance to other therapies continues to increase throughout the prostate cancer community, and we remain focused on our goal of completing ARMOR3-SV as rapidly as possible.”

#### *2016 Galeterone Expansion Plans*

***With the ARMOR3-SV trial building momentum, Tokai now plans to expand galeterone development into broader mCRPC populations, including the initiation of two additional studies during the first half of 2016 in patients who have shown resistance following treatment with either abiraterone or enzalutamide.***

(Emphasis added.)

35. On March 10, 2016, Tokai filed an Annual Report on Form 10-K with the SEC, announcing the Company’s financial and operating results for the quarter and year ended December 31, 2015 (the “2015 10-K”). For the quarter, Tokai reported a net loss of \$11.02 million, or \$0.49 per diluted share, on zero revenue, compared to a net loss of \$6.21 million, or \$0.28 per diluted share, on zero revenue for the same period in the prior year. For 2015, Tokai reported a net loss of \$45.26 million, or \$2.01 per diluted share, on zero revenue, compared to a net loss of \$23.30 million, or \$3.60 per diluted share, on zero revenue for 2014.

36. In the 2015 10-K, Tokai stated, in part:

We are conducting a pivotal Phase 3 clinical trial comparing galeterone to Xtandi® (enzalutamide) in approximately 148 treatment-naïve mCRPC patients whose prostate tumors express the AR-V7 splice variant. We refer to this clinical trial as ARMOR3-SV. We believe that the AR-V7 splice variant is the most common form of C-terminal loss, or the loss of the portion of the androgen receptor that contains the ligand-binding domain. C-terminal loss generally, and AR-V7 specifically, has been associated with poor responsiveness to commonly-used oral therapies for mCRPC. ARMOR3-SV is, to our knowledge, the first precision-medicine based

pivotal clinical trial in prostate cancer. Selection of patients with AR-V7 is made using a clinical trial assay developed by our collaborator, Qiagen Manchester Limited, or Qiagen. We believe that the design of ARMOR3-SV is aligned with feedback that we obtained from the U.S. Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA. We expect to complete enrollment in ARMOR3-SV by the end of 2016 and to have top-line data available from the study by mid-2017. We have been given fast track designation by the FDA for galeterone for the treatment of mCRPC.

...

## Our Strategy

Our goal is to become a leading biopharmaceutical company that develops and commercializes innovative therapies for the treatment of prostate cancer and other hormonally-driven disease. Our strategy includes the following components:

- *Complete the clinical development of and seek marketing approval for galeterone for the treatment of AR-V7 positive mCRPC.* ARMOR3-SV is designed to evaluate whether administration of galeterone results in a statistically significant increase in radiographic progression free survival as compared to Xtandi in approximately 148 treatment-naive mCRPC patients whose prostate tumor cells express the AR-V7 splice variant. We expect ARMOR3-SV to be fully enrolled by the end of 2016, and to have top-line data from the trial by mid-2017.

37. The 2015 10-K contained signed certifications pursuant to SOX by the Individual Defendants, stating that the financial information contained in the 2015 10-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.

38. On March 10, 2016, Tokai issued a press release entitled "Tokai Pharmaceuticals Reports Full Year 2015 Financial Results." The press release stated, in part:

**"We have made substantial progress in the last several months, executing on our Phase 3 ARMOR3-SV trial globally and expanding our galeterone development program** to include additional underserved patient populations with prostate cancer," said Jodie Morrison, President and Chief Executive Officer of Tokai. "In ARMOR3-SV, we are gaining momentum in patient screening and enrollment throughout the world. In addition, the data unlocking galeterone's distinct androgen receptor degradation mechanism presented at the ASCO Genitourinary Cancers Symposium provide further support for the differentiated profile of galeterone. **We look forward to a number of important milestones throughout 2016 and into 2017 that we expect to elucidate the broad potential of galeterone in prostate cancer.**"

Recent business highlights include:

- Progress in ARMOR3-SV, a Phase 3 registration clinical trial of galeterone in AR-V7+ mCRPC. Over 100 clinical sites in the United States, Canada, Australia and Western Europe are open and actively screening patients in ARMOR3-SV, Tokai's pivotal Phase 3 clinical trial evaluating whether administration of galeterone results in a statistically significant increase in radiographic progression free survival as compared to Xtandi® (enzalutamide) in treatment-naïve metastatic castration-resistant prostate cancer (mCRPC) patients whose prostate tumor cells express the AR-V7 splice variant. AR-V7 is a truncated form of the androgen receptor that has been associated with poor responsiveness to commonly used oral therapies for mCRPC. Screening experience in ARMOR3-SV to date indicates that the prevalence of AR-V7 continues to be in line with the company's expectations and consistent with the published literature. Enrollment in ARMOR3-SV is expected to be completed during the second half of 2016, and top-line results from the trial are anticipated by mid-2017.

(Emphases added.)

39. On May 10, 2016, Tokai filed a quarterly report on Form 10-Q with the SEC, announcing the Company's financial and operating results for the quarter ended March 31, 2016 (the "Q1 2016 10-Q"). For the quarter, Tokai reported a net loss of \$11.43 million, or \$0.51 per diluted share, on zero revenue, compared to a net loss of \$13.26 million, or \$0.59 per diluted share, on zero revenue for the same period in the prior year.

40. In the Q1 2016 10-Q, the Company stated, in part:

We are conducting a pivotal Phase 3 clinical trial comparing galeterone to Xtandi® (enzalutamide) in approximately 148 treatment-naïve mCRPC patients whose prostate tumors express the AR-V7 splice variant. We refer to this clinical trial as ARMOR3-SV. We believe that the AR-V7 splice variant is the most common form of C-terminal loss, or the loss of the portion of the androgen receptor that contains the ligand-binding domain. C-terminal loss generally, and AR-V7 specifically, has been associated with poor response to commonly-used oral therapies for mCRPC. ARMOR3-SV is, to our knowledge, the first precision-medicine based pivotal clinical trial in prostate cancer. Selection of patients with AR-V7 is made using a clinical trial assay developed by our collaborator, Qiagen Manchester Limited, or Qiagen. We believe that the design of ARMOR3-SV is aligned with feedback that we obtained from the U.S. Food and Drug Administration, or FDA, and the European Medicines Agency. We expect to complete enrollment in ARMOR3-SV by the end of 2016 and to have top-line data available from the study by mid-2017.

We have been given fast track designation by the FDA for galeterone for the treatment of mCRPC.

41. The Q1 2016 10-Q contained signed certifications pursuant to SOX by the Individual Defendants, stating that the financial information contained in the Q1 2016 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.

42. On May 10, 2016, Tokai also issued a press release entitled "Tokai Pharmaceuticals Reports First Quarter 2016 Financial Results." The press release stated, in part:

***"Over the past quarter we have made significant progress in our clinical development program for galeterone,*** as we continued to accelerate screening and enrollment in our ARMOR3-SV trial and expanded our Phase 2 trial to include additional mCRPC patients who have acquired resistance to enzalutamide," said Jodie Morrison, President and Chief Executive Officer of Tokai. "We have also strengthened our development team to sharpen focus on execution of our clinical trials, and we look forward to continued progress in the months ahead as we work with great urgency to meet the needs of patients who currently have limited therapeutic options."

Recent business highlights include:

- Progress in ARMOR3-SV, a Phase 3 registration trial of galeterone in AR-V7+ mCRPC. Patient enrollment is ongoing in ARMOR3-SV, Tokai's pivotal Phase 3 clinical trial evaluating whether administration of galeterone results in a statistically significant and clinically meaningful improvement in radiographic progression-free survival as compared to Xtandi® (enzalutamide) in treatment-naïve metastatic castration-resistant prostate cancer (mCRPC) patients whose prostate tumor cells express the AR-V7 splice variant. AR-V7 is a truncated form of the androgen receptor that has been associated with poor response to commonly-used oral therapies for mCRPC. Over 100 clinical sites in eight countries are actively screening patients for potential eligibility to participate in ARMOR3-SV. Enrollment in ARMOR3-SV is expected to be completed by the end of 2016, and top-line data from the trial are anticipated by mid-2017.

(Emphasis added.)

43. The statements referenced in ¶¶ 22-26 and 30-42 were false and/or misleading, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, these statements were false and/or misleading statements and/or failed to

disclose that: (i) there were significant structural problems with the Company's ARMOR3-SV study trial design; (ii) consequently, ARMOR3-SV was unlikely to succeed in meeting its primary endpoint; (iii) as a result, commercialization of galeterone was less likely and/or imminent than Tokai had led investors to believe; and (iv) as a result of the foregoing, the Company's financial statements, as well as Defendants' statements about Tokai's business, operations, and prospects, were false and misleading and/or lacked a reasonable basis.

### **The Truth Emerges**

49. On July 26, 2016, Tokai announced plans "to discontinue the ARMOR3-SV clinical trial, our pivotal Phase 3 study" of galeterone. The Company stated, in part:

Based on a review of all safety and efficacy data, the DMC determined that the ARMOR3-SV trial will likely not succeed in meeting its primary endpoint of demonstrating an improvement in radiographic progression-free survival ("rPFS") for galeterone versus enzalutamide in AR-V7 positive mCRPC. In making its recommendation, the DMC did not cite any safety concerns with galeterone in the trial. ARMOR3-SV is the first pivotal clinical trial in mCRPC to prospectively select AR-V7 positive patients, a population we believe represents an unmet medical need and has an aggressive disease course.

We plan to analyze the unblinded study data in detail to evaluate potential paths for galeterone and our pipeline. We plan to present data from the trial in a scientific forum once fully available and analyzed.

We also intend to evaluate our ongoing ARMOR2 expansion in mCRPC patients with acquired resistance to enzalutamide, and our planned study in patients who rapidly progress on either enzalutamide or abiraterone acetate. We plan to allow all patients currently enrolled in the ARMOR2 and ARMOR3-SV trials to continue on therapy following consultation with their physicians and study investigators. The appropriate health authorities and clinical study investigators are being notified that ARMOR3-SV is being discontinued.

50. On this news, Tokai's stock price fell \$4.10, or nearly 79%, to close at \$1.10 on July 26, 2016.

### **Post-Class-Period Disclosures**

51. On July 29, 2016, after the market closed, Tokai issued a press release entitled “Tokai Pharmaceuticals Announces Reduction in Force.” In the press release, the Company stated, in part:

Tokai Pharmaceuticals Inc. (NASDAQ: TKAI), a biopharmaceutical company focused on developing and commercializing innovative therapies for prostate cancer and other hormonally driven diseases, today announced that it is reducing its workforce by approximately 60 percent, to a total of 10 full-time equivalent employees, under a plan expected to be largely completed by the end of the third quarter of 2016. *This workforce reduction is designed to reduce operating expenses while the company conducts a comprehensive evaluation of strategic options for galeterone and its pipeline. . . .*

*“A reduction in force is a very difficult yet necessary step in light of the recent discontinuation of the ARMOR3-SV trial of galeterone in mCRPC,”* said Jodie Morrison, President and Chief Executive Officer of Tokai. “I would like to personally express my appreciation to each of the employees impacted by this decision for their commitment to the development of galeterone, as well as for their meaningful contributions to a program that has expanded the dialogue among the medical and patient communities about AR-V7 and advanced prostate cancer treatment options.”

(Emphases added.)

52. On this news, Tokai’s share price fell \$0.13, or 10.32%, to close at \$1.13 on August 1, 2016, the next trading day.

53. As a result of Defendants’ wrongful acts and omissions, and the precipitous decline in the market value of the Company’s securities, Plaintiff and other Class members have suffered significant losses and damages.

#### **CLASS ACTION ALLEGATIONS**

54. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all those who purchased or otherwise acquired Tokai’s securities during the Class Period and who were damaged thereby (the “Class”). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant

times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

55. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Tokai's securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Millions of Tokai shares were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Tokai or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

56. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

57. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

58. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

- (b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Tokai;
- (c) whether Defendants acted with scienter; and
- (d) to what extent the members of the Class have sustained damages and the proper measure of damages.

59. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

#### **UNDISCLOSED ADVERSE FACTS**

60. The market for Tokai's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures to disclose, Tokai's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired Tokai's securities relying upon the integrity of the market price of the Company's securities and market information relating to Tokai, and have been damaged thereby.

61. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Tokai's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. Said statements and omissions were materially

false and/or misleading in that they failed to disclose material adverse information and/or misrepresented the truth about Tokai's business, operations, and prospects as alleged herein.

62. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Tokai's financial well-being and prospects. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein.

#### **LOSS CAUSATION**

63. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

64. During the Class Period, Plaintiff and the Class purchased Tokai's securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

#### **SCIENTER ALLEGATIONS**

65. As alleged herein, Defendants acted with scienter in that Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, Defendants, by virtue of their receipt of information reflecting the true facts regarding Tokai, his/her control over, and/or receipt and/or modification of Tokai's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Tokai, participated in the fraudulent scheme alleged herein.

**APPLICABILITY OF PRESUMPTION OF RELIANCE  
(FRAUD-ON-THE-MARKET DOCTRINE)**

66. The market for Tokai's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Tokai's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Tokai's securities and market information relating to Tokai, and have been damaged thereby.

67. During the Class Period, the artificial inflation of Tokai's stock was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Tokai's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Tokai and its business,

operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company stock. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

68. At all relevant times, the market for Tokai's securities was an efficient market for the following reasons, among others:

- (a) Tokai stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;
- (b) As a regulated issuer, Tokai filed periodic public reports with the SEC and/or the NASDAQ;
- (c) Tokai regularly communicated with public investors *via* established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or
- (d) Tokai was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

69. As a result of the foregoing, the market for Tokai's securities promptly digested current information regarding Tokai from all publicly available sources and reflected such information in Tokai's stock price. Under these circumstances, all purchasers of Tokai's securities

during the Class Period suffered similar injury through their purchase of Tokai's securities at artificially inflated prices and a presumption of reliance applies.

**NO SAFE HARBOR**

70. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Tokai who knew that the statement was false when made.

**FIRST CLAIM**  
**Violation of Section 10(b) of**  
**The Exchange Act and Rule 10b-5**  
**Promulgated Thereunder Against All Defendants**

71. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

72. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and

other members of the Class to purchase Tokai's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

73. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Tokai's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

74. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Tokai's financial well-being and prospects, as specified herein.

75. These defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Tokai's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Tokai and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

76. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances and operations at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

77. The defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Tokai's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

78. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Tokai's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired Tokai's securities during the Class Period at artificially high prices and were damaged thereby.

79. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that Tokai was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Tokai securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

80. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

81. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

**SECOND CLAIM**  
**Violation of Section 20(a) of**  
**The Exchange Act Against the Individual Defendants**

82. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

83. The Individual Defendants acted as controlling persons of Tokai within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

84. In particular, each of these Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

85. As set forth above, Tokai and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and/or omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and

other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

- A. Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;
- B. Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and
- D. Such other and further relief as the Court may deem just and proper.

**JURY TRIAL DEMANDED**

Plaintiff hereby demands a trial by jury.

Dated: August 1, 2016

Respectfully submitted,

**POMERANTZ LLP**

*/s/ Jeremy A. Lieberman*

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